

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte FRITS JACOBUS FALLAUX, ROBERT CORNELIS HOEBEN,
ALEX JAN VAN DER EB, ABRAHAM BOUT, and DOMENICO
VALERIO

Appeal 2008-2251¹
Application 10/618,526
Technology Center 1600

Decided: June 17, 2008

Before DONALD E. ADAMS, DEMETRA J. MILLS, and JEFFREY N.
FREDMAN, *Administrative Patent Judges*.

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DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to an adenovirus packaging cell which the Examiner has rejected under the judicially created doctrine of obviousness type double patenting. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

¹ Heard May 22, 2008.

Background

“Gene therapy is a recently developed concept for which a wide range of applications can be and have been envisioned” (Spec. 1). The Specification notes that “[f]or the purpose of gene therapy, adenoviruses carrying deletions have been proposed as suitable vehicles for genetic information” (Spec. 2). The Specification indicates that “all adenovirus vectors currently used in gene therapy are believed to have a deletion in the E1 region, where novel genetic information can be introduced. The E1 deletion renders the recombinant virus replication defective” (Spec. 4).

Appellants teach that “we have developed packaging cells that have no overlapping sequences with a new basic vector and thus are suited for safe large scale production of recombinant adenoviruses” (Spec. 6).

Statement of the Case

The Claims

Claims 1, 3-7, 10, 11, 16, and 21-25 are on appeal. We will focus on claim 1, which is representative and reads as follows:

1. An isolated adenovirus packaging cell comprising in its genome:
a first nucleic acid sequence encoding adenovirus E1A and E1B gene products but lacking a nucleic acid sequence encoding adenovirus pIX.

The prior art

The Examiner relies on the following prior art references to show unpatentability:

Vogels	US 6,340,595 B1	Jan. 22, 2002
Vogels	US 6,413,776 B1	Jul. 2, 2002

The issues

The rejection as presented by the Examiner is as follows:

Claims 1, 3-7, 10, 11, 16, and 21-25 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 43 and 44 of U.S. Patent 6,340,595 and claims 7, 32, and 35 of U.S. Patent 6,413,776.

Judicially Created Obviousness Type Double Patenting rejection

Appellants raise two issues: whether the obviousness test employed should be the one way or two way test and whether the requirement for a terminal disclaimer to prevent harassment by multiple assignees is applicable.

Appellants argue that “the Federal Circuit found a two-way obviousness test appropriate under the very same circumstance relied upon for disqualification of the two-way test in this case” (App. Br. 11). Appellants state the “present application discloses an invention, PER.C6 cells, which was used in separate inventions filed in applications in July 1999 and June 1998, which issued as the '595 and '776 patents in January and July of 2002, respectively” (App. Br. 11). Appellants then contend that the “ODP rejection at issue, being based upon a one-way patentability test, ignores the precedent of *In re Braat*[, 937 F.2d 589, 590 (Fed. Cir. 1991)]. The claims on appeal are entitled to a two-way obviousness test as a matter of law” (App. Br. 11).

Appellants contend that “37 C.F.R. § 1.321(c) cannot rationally be applicable in the absence of common ownership. Otherwise, Appellant is placed in an unwarranted ‘catch 22’ situation, being both required and

forbidden to assert an ownership interest in the reference patent claims” (App. Br. 7-8). Appellants further argue that harassment by multiple assignees “cannot reasonably stand alone as justification for an ODP rejection” (App. Br. 8).

The Examiner responds that “[i]t does not logically follow from this rule [37 C.F.R. § 1.321(c)] that lack of common ownership obviates an obviousness-type double patenting rejection. Furthermore, the applications of the reference patents had been commonly assigned with the parents of the instant application” (Ans. 4).

The Examiner also contends that

[t]here is no evidence of record that the PTO prevented Appellant from including the instant claims in any of these earlier patents during their prosecution. This earlier issuance of patents over which the instant claims were obvious under obviousness-type double patenting doctrine shows that there was no administrative delay by the PTO that caused earlier issuance of applications with later effective filing dates. The instantly claimed subject matter could have been claimed and been issued in any of these earlier patents. Appellant has been solely in control of the delay in prosecution of the instant claims. Consequently, the "one- way" patentability test is applicable here, not the "two-way" test.

(Ans. 5.)

In view of these conflicting positions, we frame the judicially created double patenting issues before us as follows:

(1) Does the one way or two way test for obviousness type double patenting apply?

(2) Does the prerequisite in 37 C.F.R. § 1.321(c) for common ownership preclude requiring a terminal disclaimer when there is no common ownership?

Findings of Fact

1. Claims 43 and 44 of U.S. Patent 6,340,595 and claims 7, 32, and 35 of U.S. Patent 6,413,776 claim the use of PER.C6 cells which are rejected as anticipating, and therefore rendering obvious under the judicially created doctrine of double patenting, the currently claimed invention (*see* claims 43 and 44 of U.S. Patent 6,340,595 and claims 7, 32, and 35 of U.S. Patent 6,413,776). Appellants “acknowledge[] that the final rejections can be viewed as being in literal harmony with Chart II-B of § 804” (App. Br. 5).

2. The Examiner determined that the instant claims do not render claims 43 and 44 of U.S. Patent 6,340,595 and claims 7, 32, and 35 of U.S. Patent 6,413,776 obvious under a two-way test (Final Rejection 3/01/2006 8).

3. The instant application claims direct priority from U.S. patent application 08/793,170 which was filed March 25, 1997 and issued as U.S. Patent 5,994,128 on November 30, 1999 (*see* Spec. 2).

4. The Vogel ‘595 patent claims priority to U.S. patent application 09/097,239, which was filed on June 12, 1998 and the Vogel ‘595 patent was itself filed on July 21, 1999 and issued on January 22, 2002 (*see* Vogel ‘595).

5. The Vogel '776 patent was filed as U.S. patent application 09/097,239, which was filed on June 12, 1998 and the Vogel '776 patent issued on July 2, 2002 (*see* Vogel '776).

6. The Vogel '776 and '595 patents are not commonly owned with the instant application (App. Br. 4).

Discussion of Judicially Created Obviousness Type Double Patenting rejection

(i) *One-way test or two-way test?*

Appellants contend that the "ODP rejection at issue, being based upon a one-way patentability test, ignores the precedent of *In re Braat*. The claims on appeal are entitled to a two-way obviousness test as a matter of law" (App. Br. 11). We do not agree. When the Federal Circuit addressed this issue in *In re Berg*, 140, F.3d 1428, 1431-33 (Fed. Cir. 1998), the court stated that the two-way test is a narrow exception to the general rule of the one-way test, and that the two-way test applied when a later-filed improvement patent issues before an earlier filed basic invention. In *Berg*, the court answered the question of when the two-way test should apply and answered "[w]e hold, therefore, that if an applicant can file all of its claims in one application, but elects not to, it is not entitled to the exception of the two-way test." *In re Berg*, 140 F.3d at 1434.

We find that Appellants have presented no evidence or reason why the current claims could not have been filed in the original application in this series, U.S. patent application 08/793,170 which was filed March 25, 1997, which would have predated either of the Vogel patents (*see* FF 3-5). Since the current application is a direct child, with no continuations in part, from

08/793,170, the specification of that application necessarily provides the identical support to the claims as that provided by the instant specification. Appellants do not dispute that the one-way test would support double patenting, only arguing that the two-way test applies (FF 1-2).

Additionally, Appellants have not provided any evidence that the rates of prosecution were dictated by the USPTO. In fact, the evidence of record clearly shows that Appellants dictated the rates of prosecution, choosing to file some subject matter in U.S. application 08/793,170 filed March 25, 1997, other subject matter in a U.S. application 09/334,765, filed June 16, 1999 which was a continuation of 08/793,170, additional subject matter in U.S. application 09/506,548, filed February 12, 2000, and continuing filing in U.S. applications 10/124,414 and 10,125,751, filed April 18, 2002, as well as the instant 10/618,526 filed July 11, 2003 (*see* Spec. 2). Two of these applications matured into patents prior to the issuance of either Vogel '595 or Vogel '776 and several of the other applications were filed prior to the issuance of the Vogel '595 and Vogel '776 patents.

Berg clearly requires that the “two-way exception can only apply when the applicant could not avoid separate filings, and even then, only if the PTO controlled the rates of prosecution to cause the later filed species claims to issue before the claims for a genus in an earlier application.” *Berg*, 140 F.3d at 1435. Even if we concede that Appellants could not have avoided separate filings, due to the difference in inventorship, Appellants have provided no evidence that the USPTO controlled the rate of prosecution and the evidence of Appellants filings does not support such a finding.

We conclude that the Examiner properly applied the one-way test in light of the Federal Circuit's guidance in *Berg*.

(ii) *Common Ownership*

Section 1.321(c)(3) of 37 CFR requires a terminal disclaimer filed to overcome an obvious-type double patenting rejection include a statement that the patent shall be enforceable only as long as both patents are commonly assigned. This requirement reflects a concern that issuing patents on patentably indistinct inventions to separate patent owners may subject a purported infringer to harassment by multiple suits. *In re Van Ornum*, 686 F.2d 937, 945 (CCPA 1982) (upholding the PTO's non-alienation requirement in former 37 CFR § 1.321(b)). Strong policies dictated the creation of this principle governing the co-expiration and co-ownership of sufficiently related patents. *Pharmacia Corp. v. Par Pharmaceutical Inc.*, 417 F.3d 1369, 1374 (Fed. Cir. 2005), citing *In re Griswold*, 365 F.2d 834 (CCPA 1966) (noting the co-ownership requirement is a creative solution to potential harassment suits from two separate patents).

Indeed, the regulatory history of § 1.321 shows that the common ownership provision was added to specifically address the potential harassment of possible infringers by multiple suits:

This provision would prevent harassment of an alleged infringer by multiple parties due to subsequent different ownership of multiple patents granted as the result of filing a terminal disclaimer to overcome a double patenting rejection.

Notice of Proposed Rule Making, Conflicting Claims, 35 Fed. Reg. 20011, 20012 (December 31, 1970). The requirement for common ownership was

promulgated as part of 37 CFR § 1.321(b) (1971); Final Rule, Conflicting Claims, 36 Fed. Reg. 7312, 7312 (April 17, 1971). Section 1.321(b) is the predecessor of current § 1.321(c)(3).

The common ownership provision has been held to be a valid exercise of the Director's rule making authority in administering the statutory provision. *Van Ornum*, 686 F.2d at 944-48. As made clear by both the regulatory history of § 1.321 and the *Van Ornum* opinion, the requirement for common ownership addresses the problem of multiple infringement suits based on separate patents on patentably indistinct inventions. Interpreting the rule to permit inventions that should be subject to double patenting rejections to exclude those who lack common ownership would allow the exact situation that the regulation was intended to avoid. *See In re Van Ornum*, 686 F.2d 937, 948 (CCPA 1982) (“Upon this extensive review of the situation, we consider it desirable to tie both the termination and the ownership of the two patents together”).

Appellants concede that the instant application and the Vogel ‘595 and Vogel ‘776 patents are not commonly owned (*see* App. Br. 4). Accordingly, we hold that under the facts of this case the instant application and the Vogel ‘595 and Vogel ‘776 patents are not commonly owned as that phrase is used in 37 CFR § 1.321(c)(3). Since the terminal disclaimer must state that any patent granted on the application being examined will be enforceable only for and during the period that it and the patent to which the disclaimer is directed or the patent granted on the application to which the disclaimer is directed are commonly owned, Appellants are precluded from

overcoming the double patenting rejection by filing a terminal disclaimer.
See 37 CFR § 1.321(c); MPEP § 706.02.

Appellants argue that “37 C.F.R. § 1.321(c) cannot rationally be applicable in the absence of common ownership. Otherwise, Appellant is placed in an unwarranted ‘catch 22’ situation, being both required and forbidden to assert an ownership interest in the reference patent claims” (App. Br. 7-8). We do not agree. Appellants created the “catch 22” themselves, by choosing to delay submitting the instant claims for more than six years from the original filing date of March 25, 1997. Had Appellants filed these claims in U.S. Application 08/793,170, either the claims would have issued prior to the issuance of the Vogel ‘595 and Vogel ‘776 patent, or Appellants might have made the showing that the delays in prosecution were due to USPTO action and deserving of the two-way test. We do not think Appellants should be rewarded for dilatory filing of claims by eliminating the common ownership element of double patenting found in the patent rules.

We affirm the rejection of claim 1 under the judicially created doctrine of obviousness type double patenting. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 3-7, 10, 11, 16, and 21-25 as these claims were not argued separately.

CONCLUSION

In summary, we affirm the rejection of claim 1 the judicially created doctrine of obviousness type double patenting. Pursuant to 37 C.F.R. § 41.37(c)(1)(vii)(2006), we also affirm the rejections of claims 3-7, 10, 11, 16, and 21-25 as these claims were not argued separately.

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No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv)(2006).

AFFIRMED

dm

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